K033515

JAN 2 2 2004

November 3, 2003.

To whom it may concern:

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Trade Name - HuberPRO TM Safety Huber Infusion Set
Common Name - Huber Infusion Set
Classification Name - Intravascular Administration Set

The HuberPRO TM Safety Huber Infusion Sets are intended to be used to administer solutions and medications into vascular implant ports. In addition, to minimize the risk of accidental needle stick injury after use, the attached safety guard fully encapsulates the needle when manually activated during withdrawal. The device consists of a Protector cap, female Luer lock, PVC tubing, two each 4 inch, or one 8 inch tubing length and (.3 mm) ID, a pinch clamp, with and without a needle free y- site, a butterfly wing, a safety needle guard, an AISI 304 (19ga., 20ga., 22ga.) stainless steel needle, and a needle sheath. The components and the Processes used to manufacture these solution administration sets are substantially equivalent to like Products currently legally marketed by Horizon Medical Products, Inc. **K013871** LifeGuard TM Safety Infusion Set, and Micro Med, Inc. **K950597** Core Resistant Huber Infusion Set, The HuberPRO TM Safety Huber Infusion Sets sets will be packaged in a Tyvek/polyethylene pouch and sterilized per AAMI / ISO guidelines.

Based on the fact that the HuberPRO TM Safety Huber Infusion Sets utilizes similar and equivalent designs, components, manufacturing Processes as currently legally marketed Products, the Safety Huber Infusion Set is safe and effective when used as intended.

Best regards,
Command Medical Products

Joyce Vytlacil

Joyce Vytlacil
Operations Manager

CONFIDENTIAL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2004

Ms. Joyce Vytlacil
Operations Manager
Command Medical Products, Incorporated
15 Signal Avenue
Ormond Beach, Florida 32174

Re: K033515
Trade/Device Name: HuberPRO ™ Saftey Huber Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: December 24, 2003
Received: January 12, 2004

Dear Ms. Vytlacil:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

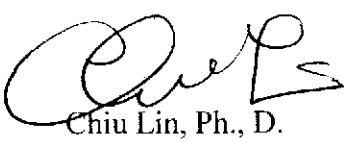
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph., D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033515

Indications for Use

510(k) Number (if known): K033515

Device Name: HuberPRO ™ Safety Huber Infusion Set

Indications For Use:

The HuberPRO ™ Safety Huber Infusion Set is intended to be used to administer solutions and medications into vascular implant ports. In addition, to minimize the risk of accidental needle stick injury after use, the attached safety guard fully encapulates the needle when manually activated during withdrawal.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Vicki Hubbard, Interim Branch Chief

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K033515